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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/740,698	12/19/2003	Sign Erickson Varner	56086 (71699)	3885
21874	7590	07/11/2006	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			HUH, BENJAMIN	
			ART UNIT	PAPER NUMBER
			3767	
DATE MAILED: 07/11/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/740,698

Applicant(s)

VARNER ET AL.

Examiner

Benjamin Huh

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/19/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 68-92 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/19/03
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 68-91 rejected under 35 U.S.C. 102(e) as being anticipated by Rosenman et al (US Patent No. 6478776 B1). The Rosenman et al reference discloses in figures 4-5 & 8-19 an implantable drug delivery device 12 comprising a non-linear shaped body member having at least two deviations from a linear and that has a shape other than a substantially C-configuration and that is implanted within a patient during use of the device to deliver a drug substance to the patient via the body member, see abstract , figures cited above, and col. 5 lines 40 – col. 12 line 23.

With respect to claims 69-71, wherein the device body member can be seen to have at least five deviations from a linear path in figures 4-5.

With respect to claims 72-73, wherein the device body comprises a helical shape and has a substantially Z-shape in figures 4-5 & 8-19.

With respect to claims 74-75, further comprising a cap element 56 that is fully capable of mating against a patient eye outer surface while the body member is inserted into the eye due to it's size, shape, and ability to work in the environment, see figures 18-19.

With respect to claims 76, wherein the device comprises a therapeutic agent for delivery to the patient during use of the device, see col. 3 line 67 – col. 4 line 32, col. 5 line 40 – col. 6 line 10, col. 15 line 9 – col. 16 line 35, & abstract.

With respect to claims 77-78, wherein the body member comprises a polymer and comprises a therapeutic substance that can be delivered to the patient eye, see col. 10 lines 21-36 & col. 15 line 9 – col. 16 line 35.

With respect to claims 79-82, the reference disclosing an implantable drug delivery device comprising a coil-shaped body member 12 that is fully capable of being implanted within an eye during use of the device to deliver a drug substance to the patient via the body member due to it's size, shape and ability to work in the environment, also see abstract, figures 4-5 & 8-19, and col. 5 lines 40 – col. 12 line 23

With respect to claims 83-88, the reference also discloses the method for treating a patient comprising providing a delivery device comprising a helical, substantially Z-shaped, body member 12 having at least five deviations from a linear path and that has a shape other than a substantially C-configuration; and inserting into a patient the device whereby the body member resides in the patient and a therapeutic substance is administered to the patient via the body member, see abstract, col. 3 line 67 – col. 4 line 32, col. 5 lines 40 – col. 12 line 23, figures 4-5 & 8-19.

With respect to claim 89, see col. 16 lines 15-35.

With respect to claim 90-91, wherein the body member comprises a polymer and comprises a therapeutic substance that can be delivered to the patient eye, see col. 10 lines 21-36 & col. 15 line 9 – col. 16 line 35.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al (US Patent No. 6478776 B1) in view of Johnson (US Patent No. 5972027). Now even though Rosenman does not explicitly disclose the device comprising a shape memory material attention is directed to Johnson. The Johnson reference teaches an implantable drug delivery device with a non-linear shaped body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium, see col. 2 lines 39-56. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device and use of Rosenman to utilize the teachings of Johnson to comprise the device of a shape memory material in order to provide a bio-compatible and strong device.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*